REMARKS

Claims 1, 10, 16, 17, 20-24, 31, 32, and 45-68 are pending. Claim 68 is amended; the claim amendment is support by the specification, for example, at paragraphs [0076] and [0077].

35 U.S.C. 102 Rejection

Reconsideration is respectfully requested of the rejection of claims 1, 10, 16, 20-24, 31, 46-48, 51-55, and 61-68 as anticipated by Gardon et al. (U.S. Patent No. 3,874,907) under 35 U.S.C. § 102. Claim 1 is directed to a pharmaceutical composition comprising a pharmaceutically acceptable excipient and core-shell particles. These core-shell particles comprise a core component and a shell component; the core component comprises a potassium-binding cation exchange polymer and the shell component comprises a crosslinked polymer produced by free radical polymerization of an ethylenic monomer.

Gardon et al. disclose microparticles for use in separating urea from saline solutions in artificial dialysis machines or ultrafiltration kidney machines. These microparticles have a core polymer of crosslinked polymer with sulphonic acid groups and a polymer skin coating that contains quaternary ammonium groups.

Gardon et al. do not disclose the pharmaceutical composition of claim 1 which requires a core-shell particle *and* a pharmaceutically acceptable incipient. Gardon et al. merely disclose microparticles that are used ***in kidney or dialysis machines***; they are not administered directly to a patient. Thus, Gardon et al. do not disclose the pharmaceutical composition comprising a pharmaceutically acceptable incipient required by claim 1.

Claim 68 is directed to a pharmaceutical composition comprising a pharmaceutically acceptable excipient and core-shell particles. These core-shell particles comprise a core component and a shell component. The core component comprises a potassium-binding cation exchange polymer. The shell component comprises a polymer produced by polymerization of an acrylic or methacrylic monomer wherein the shell component is about 0.005 microns to about 20 microns thick and the core-shell particle size is about 200 nm to about 2 mm. Claim 68 is not anticipated by Gardon et al. for the same reasons as claim 1.

In summary, claims 10, 16, 20-24, 31, 46-48, 51-55, and 61-67 depend directly or indirectly from claim 1, incorporate all the elements of claim 1, and accordingly, are not

anticipated for the same reasons as claim 1. Therefore, claims 1, 10, 16, 20-24, 31, 46-48, 51-55, and 61-68 are not anticipated by Gardon et al. (U.S. Patent No. 3,874,907) under 35 U.S.C. § 102.

35 U.S.C. 103 Rejection

Reconsideration is respectfully requested of the rejection of claim 1, 32, 45, 49, 50, and 56-60 as unpatentable Gardon et al. (U.S. Patent No. 3,874,907) in view of Warchol et al. (U.S. Patent No. 5,413,782) under 35 U.S.C. § 103(a).

As noted above, Gardon et al. do not disclose pharmaceutical compositions comprising pharmaceutically acceptable excipients. Gardon et al. do not disclose *administering* their microparticles to an animal. They merely use them in kidney or dialysis machines where the use of certain microcapsules to remove "undesirable products, such as urea."[1] Furthermore, "these microcapsules possess a high urea/salt selectivity, that is to say that they retain urea whilst *being rather impermeable to* ***salt***."[2]

Further, Warchol et al. merely disclose anion exchange polymers used as delivery systems for anionic therapeutic agents, particularly theophylline. These anion exchange polymer-drug complexes can also be coated with an enteric coating when sustained release of the therapeutic agent is desired. The enteric coating protects the anion exchange polymer-drug complex from competing anions present particularly in the stomach. These competing anions could compete for the anion binding sites on the anion exchange polymer and prematurely displace the therapeutic drug of the complex.

In contrast, claim 45 is directed to a method of removing potassium in which a composition containing a core-shell particle is administered to an animal. With all due respect, a person of ordinary skill could not arrive at the invention defined by claim 45 in view of Gardon et al. and Warchol et al. Gardon et al. employ a microcapsule to remove ***urea***, ex vivo, a microcapsule that possesses a high urea/salt selectivity and *is rather impermeable to* ***salt***." If anything, Gardon et al. would lead a person away from the claimed invention despite what

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[1] Gardon et al. (U.S. Patent No. 3,874,907) at column 2, lines 9-18 and column 14, lines 12-15.

[2] Id. at column 14, lines 16-18, emphasis added.

Warchol et al. disclose. Stated differently, a person of ordinary skill would not be led to administer Gardon et al.'s urea-binding/salt-impermeable microcapsules to an animal to bind potassium just because Warchol used anion exchange resins to deliver theophylline or other therapeutics. Thus, claim 45 in patentable in view of the cited references.

Similarly, a person of ordinary skill would not have incorporated Gardon et al.'s ex-vivo urea-binding/salt-impermeable microcapsules into a pharmaceutical composition to arrive at the composition of claim 1 just because Warchol used anion exchange resins to deliver theophylline or other therapeutics. It is clear that Gardon et al. intended their microcapsules for ex vivo use and nothing in Gardon et al. or Warchol et al. would suggest a systemic administration.

The polymer-drug pharmaceutical complex described by Warchol et al. provided sustained release of the drug in some embodiments. The timed release embodiment included an enteric coating that prevented anions in the stomach and upper gastrointestinal tract from displacing the anionic drug from the anion exchange polymer before the enteric coating was disintegrated. Once the complex reached the portion of the gastrointestinal tract where the enteric coating was disintegrated, anions could displace the anionic drug, which could in turn be absorbed into the system. These drug delivery polymers would not have provided a reason for a skilled person to administer the Gardon microparticles to bind potassium. Neither of the references discloses potassium nor do they suggest alone or in combination that the Gardon microparticles would be effective in binding potassium. The core-shell particles in the instant claims are therapeutic agents and remove cationic species, particularly potassium, from the gastrointestinal tract. This problem is different from the anionic polymers of Warchol acting as drug delivery agents. The Office's assertion is the product of impermissible hindsight reasoning using applicant's claims as a template. Thus, claim 1 is patentable in view of the cited references under 35 U.S.C. § 103(a).

In conclusion, claims 1, 45, and the claims that depend therefrom, are patentable in view of the cited references. Applicants respectfully request that this basis for rejection be withdrawn.

Provisional Double Patenting Rejection

The Office provisionally rejects claims 1, 10, 16, 17, 20-24, 31, 32, and 45-65 on the ground of nonstatutory obvious-type double patenting over claims 3, 4, 14, 15, 18-22, 29, 30, 34,

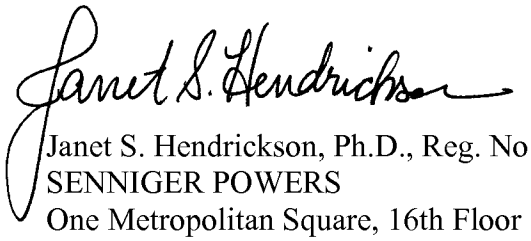
36, 40, and 51-75 of copending U.S. Serial No. 10/814,749. Without conceding the propriety of this rejection, applicant will consider filing a terminal disclaimer to obviate this basis for rejection when the application is otherwise in condition for allowance.

CONCLUSION

Applicant submits that the present application is now in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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